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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/770,241	02/02/2004	James A. Laugham JR.	07985-031002	9463
26161	7590	09/27/2005		
FISH & RICHARDSON PC P.O. BOX 1022 MINNEAPOLIS, MN 55440-1022			EXAMINER MCKANE, ELIZABETH L	
			ART UNIT	PAPER NUMBER

1744

DATE MAILED: 09/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/770,241

Applicant(s)

LAUGHARN ET AL.

Examiner

Leigh McKane

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 08 July 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,2,6,7,9-14 and 32-37 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,6,7,9-14 and 32-37 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 7 and 36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 7, line 1, “the desired biomolecule” lacks positive antecedent basis as no such element has yet been claims.

In claim 36, “the infectious agent” lacks positive antecedent basis as no such agent has been previously recited.

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1, 2, 6, 7, 9-14, and 32-37 are rejected under 35 U.S.C. 102(b) as being anticipated by Hashizume et al (“Kinetic Analysis of Yeast Inactivation by High Pressure Treatment at Low Temperatures”) in view of Hayakawa et al (“Oscillatory Compared with Continuous High Pressure Sterilization on *Bacillus stearothermophilus* Spores”).

With respect to claims 1, 2, 6, 7, , 9, 10, 13, 14, 32-35, and 37, Hashizume et al teaches a method for sterilizing a foodstuff material (which contains desired biomolecules such as nutrients, proteins, carbohydrates, etc.) wherein the material is provided at ambient conditions, exposed to an elevated pressure of 120 and 300 MPA (17400 and 43500 psi), and the pressure released. Since the pressure of Hashizume et al is within the range claimed, it is insufficient to irreversibly denature proteins. The material is preferably at a temperature of -20° to 50 °C before pressurization. See page 1455. The material of Hashizume et al is initially contaminated with yeast (fungus). Moreover, the Temperature-Pressure Diagram in Figure 4 of Hashizume et al illustrates that pressure inactivation improves as the temperature either drops below -20 °C or rises above 40 °C. Both temperatures are “below 45 °C”, as claimed.

Hashizume et al discloses a continuous application of high pressure upon the sample and does not disclose repeatedly cycling the pressure. However, this concept is evidenced by Hayakawa et al, who discloses that oscillatory (cyclic) pressurization is more effective than continuous pressurization in sterilizing resistant microorganisms (spores). See Abstract. Since Hashizume et al envisions use of the high pressure treatment on all types of microorganisms, not just yeasts, it would have been obvious to use the cyclic pressurization of Hayakawa et al in the method of Hashizume et al, in order to destroy resistant microorganisms as well. Moreover, it would have been obvious to optimize the number of cycles and the pressure differential, as such is readily determinable through routine experimentation.

As to claims 11 and 12, since Hashizume et al discloses treating the material at a temperature from -20 ° to 50 °C, it would have been obvious to bring it to this temperature by warming if the material is initially in a deep frozen state. Similarly, when the product must be

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first cooled before treatment in order to bring it within the necessary temperature range, it would have been obvious to warm it after treatment, to bring it back up to its original temperature.

With respect to claim 36, it is deemed obvious to one of ordinary skill in the art to apply the method of Hashizume et al with Hayakawa et al to the sterilization of all types of microorganisms as one would have had an expectation of success when doing so as Hashizume et al envisions use of the high pressure treatment on all types of microorganisms, not just yeasts.

#### ***Claim Objections***

5. Claims 32 and 33 are objected to because of the following informalities: In claims 32 and 33, “marcromolecule” should be –macromolecule--.

#### ***Response to Arguments***

6. Applicant's arguments filed 8 July 2005 have been fully considered but they are not persuasive.

7. Applicant limits Hashizume et al's teaching to a temperature range of only above 45 °C or below 10 °C. However, the Temperature-Pressure Diagram in Figure 4 of Hashizume et al clearly illustrates that pressure inactivation improves as the temperature either drops below –20 °C or rises above 40 °C. This range encompasses temperatures “below 45 °C”. Therefore, the combination of Hashizume et al with Hayakawa et al does not involve combining a “non-preferred teaching” with that of Hayakawa et al.

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Moreover, although Applicant submits that Hayakawa's pressure cycling is only for bacterial spores, the Examiner interprets Hayakawa et al to teach that when one is sterilizing a resistant microorganism (such as a spore), pressure cycling is effective.

***Conclusion***

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh McKane whose telephone number is 571-272-1275. The examiner can normally be reached on Monday-Thursday (5:30 am-2:00 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Kim can be reached on 571-272-1142. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
**Leigh McKane**  
**Primary Examiner**  
**Art Unit 1744**

elm  
26 September 2005